

Message Text

UNCLASSIFIED

PAGE 01 STATE 073489
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 ISO-00 OES-06 COME-00
EB-08 /052 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/WE:JFDOBBINS(INFO)
ARA/ECA:RELTZ(INFO)
EUR/NE:DJDONCHI(INFO)
EUR/WE:EJBEIGEL(INFO)
EA/J:DFSMITH(INFO)

-----030909Z 043084 /22

P R 022150Z APR 77
FM SECSTATE WASHDC
TO AMCONSUL SAO PAULO PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY TOKYO
AMEMBASSY OSLO PRIORITY
INFO AMEMBASSY BRASILIA

UNCLAS STATE 073489

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BR, FR, IT, JA, NO R

SUBJECT: FDA ADVISORY-DEFECTIVE CARDIAC PACEMAKERS
(RECALL T-074-7)

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL:

PRODUCT INVOLVED:

INTERLITH LITHIUM CARDIAC PACEMAKER; MODEL 223-MOS-1; DEMAND
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TYPE. SERIAL NUMBERS 00001-01725 ARE BEING RECALLED.

MANUFACTURER/RECALLING FIRM/RESPONSIBLE FIRM:

INTERMEDICS INC.
240 TARPON INN VILLAGE
FREEPORT, TEXAS 77541

2. REASON FOR RECALL:

PACEMAKER PRODUCES AN ABNORMAL PULSE OF FULL AMPLITUDE AND A NORMAL PULSE WIDTH BETWEEN 315 AND 350 MILLISECONDS AFTER RELEASE OF A NORMALLY TIMED PULSE. THE ABNORMAL MODES OCCUR

OCCASIONALLY. AS A RESULT, 5 UNITS HAVE BEEN EXTERPATED FROM PATIENTS AS A RESULT OF THE MALFUNCTION. NO DEATHS HAVE BEEN ATTRIBUTED TO THE MALFUNCTION.

3. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED 10 MARCH 1977 REQUESTING THAT PHYSICIANS RUN EKG STRIPS ON EACH PATIENT IN WHOM IMPLANTS HAVE BEEN MADE UNLESS INTERMEDICS HAS STRIP ON FILE.

4. FOREIGN CONSIGNEES AS FOLLOWS:

MADITRONICA S.A.
RUA CANUTO DO VUL, 97
SAO PAULO - S.P.
BRAZIL

BIOMEDIX
54 RUE LABOURTE
PARIS 75015
FRANCE

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DINI ITALIA
VIALE DEPARMENTO
00144 ROMA
ITALY

MEDICAL YACHIYODA CO., LTD
2-12-15 SHIABASHI
MINATO-MU
TOKYO, JAPAN

VINGMED A/S
BAGDEHAUGSVEIEN 21 B
POST BOKS 7021
HOMANSBYEN, OSLO 3
NORWAY
VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 02-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE073489
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770115-1198
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770494/aaaadebs.tel
Line Count: 113
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 265501ab-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 05-Jan-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2916385
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY-DEFECTIVE CARDIAC PACEMAKERS (RECALL T-074-7)
TAGS: OGEN, ETRD, EIND, TBIO, BR, FR, IT, JA, NO
To: SAO PAULO PARIS MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/265501ab-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009